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IN THE

Supreme Court of the United States

OCTOBER TERM, 1988

9/1 KG CONTAINERS, MORE OR LESS, OF AN ARTICLE OF DRUG FOR VETERINARY USE, AND SCHUYLER LABORATORIES, INC.,

Petitioners,

v.

UNITED STATES OF AMERICA,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

BRIEF OF THE HUMANE SOCIETY OF THE UNITED STATES AS AMICUS CURIAE IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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CONSENT

The Humane Society of the United States has obtained written consent to file a brief as amicus curiae from Petitioner and Respondent, pursuant to Sup. Ct. R. 36.1.

INTEREST OF AMICUS CURIAE

The Humane Society of the United States ("HSUS") is a non-profit, charitable corporation, organized under the laws of the State of Delaware, with principal offices at 2100 L Street, N.W., Washington, D.C. and regional offices throughout the United States. It has an active membership of over 252,000 persons residing in every state of the United States and in the District of Columbia, and a mailing constituency of over 579,000 persons nationwide, who share a commitment to the prevention of cruelty to animals and to the promotion of all aspects of animal welfare. In the past thirty years, the HSUS has devoted considerable resources to researching and publicizing many aspects of farm and companion animal welfare. The HSUS publishes informative and educational materials relating to the humane treatment of farm and companion animals and, upon request, consults with and advises Congress as well as agencies of federal, state, and local government.

The Humane Society of the United States has a long-standing interest in the relationship between veterinarians and the animals which they treat, as well as the ethical aspects of that relationship. Apart from the interests of the Petitioner, the health and welfare of animals and of society will be strongly affected by the final disposition of this case. It is the duty of the HSUS to protect the interests of those animals which

can not, of course, protect themselves. Therefore, the outcome of this case is inextricably linked to the most fundamental charitable purposes of the HSUS.

The HSUS believes that in order to assure the humane treatment of animals and to promote the public welfare, veterinarians must have access to those bulk chemicals from which they compound a large number of the drugs used in the daily practice of veterinary medicine for the alleviation of disease and suffering in animals and therefore disagrees with the decision reached by the Seventh Circuit Court of Appeals.

SUMMARY OF ARGUMENT

The health and well-being of many numbers and species of animals will be jeopardized if the current ability of the veterinarian to prepare drugs is restricted. There exist many common diseases and conditions for which there are no FDA-approved drugs. This situation is not likely to change, because it is not cost-effective or feasible for many pharmaceutical manufacturers to test and see through to approval a significant number of commonly used and beneficial drugs for a large number of animal species. Restrictions on the use of such drugs will contribute to the needless suffering of many animals from disease and injury. In addition, specialties and research in the animal health field will be set back for many years.

The wide variety of animal species and the multitude of illnesses which may befall these animals make it necessary for the veterinarian to frequently prescribe newer, more powerful, yet not specifically labelled antibiotics and combinations thereof, in order to minimize drug residue problems while maximizing therapeutic effectiveness. Due to their highly spec-

ialized and rigorous professional training, veterinarians are uniquely qualified to make such decisions on a day-to-day basis. If the decision of the Seventh Circuit Court of Appeals is allowed to stand, there will be grave implications for the veterinary profession and its ability to treat animals effectively. Due to the requirement of approval, it is likely that a veterinarian could be held liable if an animal were to die after being treated with an unapproved drug, yet in many cases such treatment may be necessary in order to alleviate an animal's suffering or to save its life. The fear of being sued will thus produce the deleterious effect of causing suffering and loss of animals that might otherwise have been prevented. Other aspects of public policy also support reversal of the decision reached by the Seventh Circuit Court of Appeals. In order to prevent the entry of diseased animals into the stream of commerce, it is necessary for veterinarians to be able to prescribe and administer drugs as is deemed necessary. Factory farming leads to diminished resistance to disease and to increases in the number of injuries sustained by food animals, ever requiring the veterinarian to prescribe new drugs and combinations thereof.

There are also obvious anti-competitive aspects to the outcome of this case. The requirement of FDA approval will cause smaller pharmaceutical companies to abandon their animal drug business, leading to a critical narrowing of the veterinary pharmacopeia. There will be no appropriate drugs for some species or diseases, which will cause unnecessary suffering and death to animals and will threaten the public welfare. For all of these reasons, the decision reached

by the Seventh Circuit Court of Appeals is clearly against the larger interests of society.

ARGUMENT

I. CURRENT VETERINARY PRACTICES ARE NECESSARY TO ALLEVIATE ANIMAL SUFFERING AND PREVENT UNNECESSARY DEATHS

As argued below in Part II, the veterinarian has a moral and ethical responsibility to protect the animal's interests, and the animal should thus receive the best possible veterinary treatment to alleviate suffering and illness. A limitation on the ability of the veterinary profession to practice as it thinks best will contribute to the suffering of countless animals due to loss of the veterinarian's power to prescribe many extremely beneficial drugs and treatments. In taking its current position, the FDA places the welfare of animals in jeopardy, by violating the animal's interest in receiving the best and most appropriate veterinary treatment that the client is willing and able to pay for.

There are a number of commonly encountered diseases afflicting both food and companion animals which cannot be treated with currently approved drugs, but which are regularly treated with unapproved drugs. In beef or dairy cattle, there are a number of regularly occurring health problems for which there simply is no FDA-approved drug which is effective. For example, there are no approved tranquilizers which can be used to restrain beef cattle which are in labor and need to be restrained. Thus, the use of Rompun, which is only approved for use in horses, may be necessary. *Verified Statement of J.J. Crouch, D.V.M.* (April 15, 1987) at 2-3, *submitted*

in, Cowdin v. Young, Case No. 87-0912F_(W.D.La. 1987).

In the treatment of acute coliform mastitis, an inflamation of the mammary gland due to infection, the determination of the amount and type of drugs used must be calculated "in proportion to the animal's reaction to the endotoxin being produced by the bacteremia, and the approved labels for drugs to treat this condition simply can not take this factor into account;" Gentamicin and Banamine are often the most effective drugs but are approved only for horses. *Id.,* at 3; *Verified Statement of Mark F. Hemmerich, D.V.M.* (April 15, 1987) at 2, *submitted in, Cowdin v. Young, supra.* Another highly prevalent condition is respiratory infection due to *Pasteurella haemolytica* and *Pasteurella multocida.* This condition can spread rapidly in winter if there is high humidity and fairly mild weather because the cattle are kept close together in barns. If only approved medications were used for treatment, as many as 75% to 80% of those afflicted would die. *Verified Statement of Douglas M. VanDamme, D.V.M.* (April 15, 1987) at 2, *submitted in, Cowdin v, Young, supra.*

In swine, coccidiosis is a common condition. This disease may cause neonatal scours in pigs that can kill up to 50% of the baby pigs in a farrowing; it can only be effectively treated with unapproved bovine coccidiostats in the swine ration or administered orally to the baby pigs. Without these drugs, 10% to 15% of a swine herd may be lost. *Verified Statement of Michael B. Davis, D.V.M.* (April 27, 1987) at 1, *submitted in, Cowdin v. Young, supra.* There are no approved treatments for colibacillosis (baby pig diarrhea) despite the fact that this disease occurs on most

hog-producing farms and that rapid antibiotic resistance is common. *Verified Statement of Wiley R. McVicker, D.V.M.*, (April 28, 1987) at 2, *submitted in, Cowdin v. Young, supra.*

In goats, the FDA has only approved wormers such as Atrobine and Neomycin; for approximately 90% of the conditions and disorders in goats there are no approved drugs. *Verified Statement of Robert M. Clack, D.V.M.* (April 28, 1987) at 3, *submitted in, Cowdin v. Young, supra.* There are no approved anesthetics available for goats. *Statement of Wiley R. McVicker, D.V.M.* (April 28, 1987) at 2, *submitted in, Cowdin v. Young, supra.* There are no approved drugs to treat *any* known diseases in buffalo. *Id.*, at 3. The well-documented lack of effective approved anesthetics for use in any animals (five of the veterinarians who submitted verified statements in *Cowdin v. Young* stated that there are no effective approved anesthetics for any animals) means that an unconscionable situation will exist if the FDA adheres to its new policy—animals will be subjected to surgery without anesthesia or will suffer and die.

Veterinarians find it necessary to use even those drugs which are FDA-approved in a manner other than that in which they are approved. For example, the approved label dosage for procaine penicillin aqueous injection is 3,000 units per pound of body weight, but for various disease conditions the effective dosage may be 20,000 to 60,000 units per pound. *Verified Statement of Daniel J. Lohnes, D.V.M* (April 28, 1987) at 1, *submitted in Cowdin v. Young, supra.* The approved dosage of oxytetracycline hydrochloride injection is far too low to effectively treat shipping fever pneumonia in cattle. *Id.*, at 1-2. Bacteria con-

tinue to develop resistance to antibiotics, while the FDA-approved dosages remain static, precluding effective treatment.

Several drugs approved for use in humans but not in animals are necessary to treat commonly encountered illnesses in companion animals. Tapazole, a human medicine for hyperthyroidism, is used on the increasing number of cats which suffer from this condition. Tussigon is a human medicine used on dogs with a common cough. Hydroxyzine hydrochlorate, an antihistamine for humans, is also used to treat dogs with severe pruritis (itching); without this treatment, many dogs would scratch themselves until they bleed. *Statement of Carvel G. Tiekert, D.V.M., President of the American Veterinary Holistic Medical Association* (December 1, 1988). Despite the common incidence of diabetes in companion animals, no form of insulin is approved for use in animals.

It is simply not cost-effective or feasible for small pharmaceutical manufacturers to test and see through to approval a significant number of commonly used and beneficial veterinary pharmaceuticals for a large number of animal species. Thus, this new FDA approach to the use of bulk drugs will not only place millions of farm and companion animals, such as cattle, horses, cats, and dogs, outside the domain of competent and appropriate treatment, it will also place at risk many species of wildlife needing veterinary treatment. Pet rabbits and gerbils, parakeets and parrots, iguanas and ferrets, zoo- and ranch-raised wildlife of all kinds, buffalo and antelope, foxes and chinchillas will also be placed in jeopardy, unless the veterinarian is able to exercise his or her discretion

over the use of pharmaceuticals not yet approved for use.

Recently emerging veterinary specialties, such as oncology, opthalmology and cardiology which rely heavily upon the use of drugs only approved by the FDA for human use will be set back many years. The astronomical financial burden imposed by the FDA's requiring approval of the use of all drugs on all species will render it difficult for any new areas of animal medical care to be explored. (Due to the new policy of heavy-handed intervention on the part of the FDA, it will be difficult enough for veterinarians to use those techniques and drugs that have been proven over time.)

By making the use of many extremely beneficial drugs suddenly off limits, the FDA will contribute to the needless suffering of farm animals from disease and injury. Animals will be untreated or left to die, or necessary surgery will be performed without anesthesia. The policy being pursued by the FDA will gravely and unnecessarily endanger the lives of millions of animals and may endanger the very existence of many species. The FDA's goals would be better served if the FDA would take measures to restrict lay use of animal drugs by farmers who lack professional training and are more concerned with profits than with their animals or the public health.

II. THE ROLE OF VETERINARIANS IN OUR SOCIETY REQUIRES THEIR BEING ABLE TO TREAT ANIMALS WITH MIXTURES OF BULK CHEMICALS IN ACCORDANCE WITH LONG-STANDING PRACTICE

Before the significance and consequences of the ruling of the Seventh Circuit Court of Appeals can be

adequately and objectively reconsidered, the role of the veterinarian in society, and in animal agriculture in particular, must be taken into account. The practitioner of the veterinary sciences has very strong ethical and professional obligations both to society and to the animals which he or she treats.

The role of the veterinarian is multi-faceted and complex, as reflected in the *Veterinarian's Oath* where the animal doctor pledges to use his or her skills:

> . . . for the benefit of society through the protection of animal health, the relief of animal suffering, the conservation of livestock resources, the promotion of public health, and the advancement of medical knowledge.
>
> I will practice my profession conscientiously, with dignity, and in keeping with the principles of veterinary medical ethics.

N.E.Hutton, "Animal Welfare: An AVMA Perspective," *California Veterinarian*, Jan. 1983, at 31.

From the perspective of veterinary ethics, this means that veterinarians must recognize their responsibilities to their clients, to society generally, and to their animal patients. Occasionally, the demands the client or of society may conflict with the best interests of the animal patient, but the veterinarian nonetheless has a moral obligation and an ethical responsibility to protect the animal's basic interest in humane consideration and to be the recipient of the best possible treatment for the alleviation of suffering and sickness. *See*, M.W. Fox, "Veterinarians and Animal Rights," *California Veterinarian*, Jan. 1983, at 15. The American Veterinary Medical Association

(AVMA) has recognized the obligation of the veterinarian not only to society, but to animals as well. In 1981, the AVMA Animal Welfare Committee adopted as a guiding principle that "AVMA has a long-term concern and commitment to the welfare and humane treatment and care of animals." See, N.E. Hutton, *supra*, at 31. The balance between serving the best interests of the public/client and the animal/patient is clearly a delicate one that entails both subjective and objective judgment by the veterinarian.

Due to the wide variety of animal species and the multitude of illnesses which may afflict these species, veterinarians must frequently prescribe newer, more powerful, yet not specifically labelled antibiotics and combinations thereof, to minimize drug residue problems while maximizing therapeutic effectiveness. Veterinarians are uniquely qualified to make such decisions on a day-to-day basis. Veterinarians must undergo a great deal of educational preparation to practice. All states require licensing, and to become licensed a veterinarian "must have a degree from an accredited college of veterinary medicine, and pass a thorough examination given by a state's board of examiners." *Animal Health Technology* 451 (E.J. Catcott 2d ed. 1977). To earn the degree of Doctor of Veterinary Medicine (D.V.M.), the veterinarian must complete a minimum of two years pre-veterinary college study, followed by four years of professional education. Professional journals, consultation with collegues, continuing education and post-graduate education also keep the veterinarian informed as to developments in the field. *Id.*, at 452-453.

"As the veterinarian because of his specific training and experience should be the major interpreter of the

relevance of animal disease to the human population, he must play an important part in the formulation of disease control policies which have a public health purpose." Brander, "The Relevance of Human and Animal Health Considerations in Veterinary Education," *Veterinary Epidemiology and Economics* 325 (1980). The veterinarian is the key figure in the assurance of drug safety. The pharmaceutical company may manufacture a safe product, and one which has been approved by the FDA, but if the veterinarian does not use the drug properly in treating his or her patients then no amount of FDA approval will assure animal or public health. It is thus clear that the FDA policy is not only obstrusive and heavy-handed, but is ill-suited to achieve its goals.

If the FDA prevails in its attempts to require FDA approval of the drugs involved in this case and to control the manner in which veterinarians compound medicines for use in the course of their professional practices, the result will be disastrous for the veterinary profession. A veterinarian could be held liable if an animal were to die after being treated with an unapproved drug or one that was not specifically labelled for use on that animal's species. However, in many cases, such treatment may be necessary to alleviate the animal's suffering, or to save its life. The fear of being sued will produce the deleterious effect of causing suffering and loss of animals that would have otherwise been spared. Restrictions on the ability of veterinarians to practice as they deem necessary will only hurt the animal population and society as a whole. Unless the veterinarian is allowed to exercise his or her discretion over the use of pharmaceuticals not yet approved for use, society and the

veterinarian's animal patients will suffer and the veterinarian will not be able to live up to the standards imposed by his or her sacred oath.

III. PUBLIC POLICY MILITATES AGAINST THE REQUIREMENT OF FDA APPROVAL OF EVERY DRUG USED IN THE PRACTICE OF VETERINARY MEDICINE

The Amicus Curiae recognizes and supports the FDA's interest in protecting the public health and welfare. However, the policy apparently adopted by the FDA to deal with those health hazards, illustrated by FDA actions which precipitated this case, is ill-suited to achieve these goals. In order to prevent the entry of diseased food animals into the stream of commerce, it is crucial for veterinarians to be permitted to prescribe antibiotics as they deem necessary. "It is . . . a responsibility of the veterinarian to be a source of knowledge on the animal diseases which could cause an epidemic of disease in human beings." Brander, *supra*, at 321. "There are approximately 250 diseases which are considered zoonotic, i.e. can spread from animal to man, although many of them are not readily transmitted to man because they predominate in wild animals or in small rodents, there are a significant number which are always potentially transmissable and which can be controlled by preventative methods . . . both the effective use of drugs, vaccines and disinfectants, and . . . also on a mutual understanding of both epidemiology and the relevance of therapy." *Id.*, at 324.

The widespread use of "factory farming"—practices involving the raising of food animals in massed, crowded conditions designed to maximize economies of scale—has resulted in impaired immunity and

unique health hazards in food animals. Factory farm animal experts have observed that animals in the factory farm setting become "stressed," and react to this stress by burning up "energy and nutrients that would otherwise go toward growth, gestation, lactation, and disease resistance . . . When an animal is stressed, its defenses are down and it is more prone to infectious diseases . . . the stressed animal may catch a disease which spreads to the second animal." J. Mason & P. Singer, *Animal Factories* 21-23 (1980). The crowded conditions of the factory farm setting increase the likelihood and frequency of fighting, which also causes injury. *Id.*, at 23. Pig and dairy factories are susceptible to diseases aggravated by the factory farming conditions. *Id.*, at 25. Calves raised for veal suffer from the effects of deliberately-induced anemia, which results in decreased resistance to disease. *Id.*, at 27. *See also, generally*, Brander, *supra*, at 319-324.

Because of this, it is increasingly necessary for veterinarians to prescribe newer, more powerful antibiotics and combinations thereof, although many of these have not been specifically labelled for use on the particular species being treated.* While the FDA

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* One British veterinarian has observed the necessity of regularly introducing new antibiotics to treat animal infections which might otherwise spread to humans as the animals are consumed by humans:

> If an animal is fed antibiotics the organisms in the gut may duly develop resistance to that antibiotic, or antibiotics. If, however, those antibiotics are no longer administered to the animal, the organisms in the gut continue to remain drug resistant. Should that animal acquire a salmonella infection the drug resistance of

approval process may be sufficient to cope with the testing and approval of drugs used on humans, a number of critical problems will be created by the requirement of testing and approval of a large number of drugs, to be used for treatment of an even larger variety of illnesses, and to be applied to a multitude of species.

Moreover, there are also obvious anti-competitive aspects to the requirement of FDA approval and labeling. It would not be cost-effective or economically feasible for smaller pharmaceutical companies to conduct tests on the various species in order to conform with FDA protocols prior to approval for use in specified animal species. This will lead to the demise of many small veterinary biologics companies and to a critical and tragic narrowing of the veterinary pharmacopeia. It will also inevitably lead to control over production of a limited spectrum of veterinary drugs by the small number of pharmaceutical companies which possess the almost unlimited resources necessary to conduct new product tests on various species for FDA-approved labeling.

An "orphan" drug problem, as in human medicine, is also then likely to arise where no appropriate med-

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> those organisms already present can be passed over to the new infecting salmonella. Should the salmonella acquired by the animal cause illness in that animal, the giving of antibiotics to which the organism has acquired its resistance will not only have no therapeutic effect whatsoever, but will probably make the animal's condition worse by destroying those organisms already in the bowel which may not have required antibiotic resistance.

D.J.H. Payne, "Medical Opinion on Antibiotics in Agriculture," *Factory Farming* 26 (1970).

ications are available on the market for some species and disease conditions because they are no longer being manufactured. These occurrences would threaten not only the welfare of companion and farm animals: advances in the fields of comparative medicine and therapeutics would also be slowed dramatically. This would have negative social consequences since many advances in human medicine are made from veterinary clinical studies on sick animals, most notably regarding cancer and immune-deficiency diseases. *See, Animal Health Technology, supra,* at 451. Therefore, the requirement of FDA approval of drugs such as those involved in this litigation is clearly against the larger interests of society.

CONCLUSION

The FDA should not be empowered to completely control the manner in which veterinarians may compound medicines for use in their veterinary practices. In order for veterinarians to serve society and their animal patients, the regulatory requirement that the drugs they commonly use bear specific directions for use must be interpreted so as to avoid the consequences described above. Any decision otherwise would senselessly limit the spectrum of drugs which veterinary practioners may use, and would make the FDA alone the sole authority over which drugs private veterinarians may give to their animal patients. The FDA would thus clearly be imposing on the ability of veterinarians to practice their healing art.

The harm that such a policy would cause to the many far outweighs any benefits that a restrictive regulatory policy would provide. Millions of animals will suffer and die, with attendant consequences to

the food supply. For all of these reasons, as well as those reasons set forth in the brief of Petitioner, Schuyler Laboratories, Inc., this Court should exercise its discretion to review the decision reached by the Seventh Circuit Court of Appeals.

Respectfully submitted,

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